

**§ 85.11 Notification of determination to employers, affected employees and Department of Labor.**

(a) Upon conclusion of an investigation, NIOSH will make a determination concerning the potentially toxic or hazardous effects of each substance or physical agent investigated as a result of the request for health hazard evaluation. At a minimum, the determination will: (1) Identify each substance or physical agent involved and describe, where appropriate, the concentrations or levels of the substance or physical agent found in the place of employment and the conditions of use, and (2) state whether each substance or physical agent has potentially toxic or hazardous effects in the concentrations or levels found, as well as the basis for the judgments.

(b) Copies of the determination will be mailed to the employer and to the authorized representatives of employees.

(c) Except as hereinafter provided, the employer shall post a copy of the determination for a period of 30 calendar days at or near the workplace(s) of affected employees. The employer shall take steps to insure that the posted determinations are not altered, defaced, or covered by other material during such period. The employer will not be required to post the determination if the employer requests that copies of the determination be mailed to affected employees and furnishes NIOSH with a list of the names and mailing addresses of the employees employed in the workplace(s) designated by the NIOSH Officer. In the latter event, NIOSH will mail such copies to affected employees at the mailing addresses provided by the employer.

(d) For purposes of this section, the term “affected employees” means those employees determined by NIOSH to be exposed to the substance(s) or physical agent(s) which is the subject of the health hazard evaluation.

(e) Copies of determinations made under the OSH Act will be forwarded to the Department of Labor and the appropriate State agency designated under section 18(b) of the OSH Act. Copies of determinations made under the FMSH Act will be forwarded to the Mine Safety and Health Administra-

tion of the Department of Labor; the Bureau of Mines, Department of the Interior; and the State agency which, in the judgment of NIOSH, would benefit the most from the information. If NIOSH determines that any substance or physical agent has potentially toxic or hazardous effects at the concentrations or levels at which it is used or found in a place of employment, and the substance or physical agent is not covered by a safety or health standard established under section 6 of the OSH Act or section 101 of the FMSH Act, NIOSH will immediately submit the determination to the Secretary of Labor, together with all pertinent criteria.

[37 FR 23640, Nov. 7, 1972, as amended at 45 FR 2653, Jan. 14, 1980]

**§ 85.12 Subsequent requests for health hazard evaluations.**

If a request is received for a health hazard evaluation in a place of employment in which an evaluation under this part was made previously, NIOSH may make another investigation if, as a result of the passage of time or additional information, another investigation would be consistent with the purposes of the Acts.

[45 FR 2654, Jan. 14, 1980]

**PART 85a—OCCUPATIONAL SAFETY AND HEALTH INVESTIGATIONS OF PLACES OF EMPLOYMENT**

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AUTHORITY: Sec. 8(g), 84 Stat. 1600; 29 U.S.C. 657(g) and sec. 508, 83 Stat. 803; 30 U.S.C. 957.

**§ 85a.1 Applicability.**

(a) Except as otherwise provided in paragraph (b) of this section, the provisions of this part apply to investigations of places of employment which are conducted by NIOSH under sections 20 and 8 of the Occupational Safety and Health Act of 1970 and sections 501 and 103 of the Federal Mine Safety and Health Act of 1977.

(b) The provisions of this part do not apply to those activities covered by part 85 of this chapter.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]

**§ 85a.2 Definitions.**

Any term defined in the Occupational Safety and Health Act of 1970 or the Federal Mine Safety and Health Act of 1977 and not defined below shall have the meaning given it in the Acts. As used in this part:

(a) *OSH Act* means the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*) and *FMSH Act* means the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 *et seq.*).

(b) *Assistant Regional Director* means any one of the ten Occupational Safety and Health Administration Assistant Regional Directors for Occupational Safety and Health.

(c) *Informed consent* means the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The basic elements of information necessary to such consent include:

(1) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

(2) A description of any attendant discomforts and risks reasonably to be expected;

(3) A description of any benefits reasonably to be expected;

(4) A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) An offer to answer any inquiries concerning the procedures; and

(6) An instruction that the person is free to withdraw his consent and to discontinue participation in the investigation any time without prejudice to the subject.

(d) *Investigation* means research projects, experiments, demonstrations, studies, and similar activities of NIOSH which are conducted under section 20 of the OSH Act and section 501 of the FMSH Act.

(e) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to such subject's participation in the particular activity or procedure.

(f) *NIOSH* means the National Institute for Occupational Safety and Health of the Center for Disease Control, Public Health Service, Department of Health and Human Services.

(g) *NIOSH authorized representative* means a person authorized by NIOSH to conduct investigations of places of employment, including any person that is fulfilling a contract agreement with NIOSH or is serving as an expert or consultant to NIOSH pursuant to the Act.

(h) *NIOSH Regional Office* means any one of the ten Department of Health and Human Services Regional Offices, the addresses of which are specified in § 5.31 of title 45, Code of Federal Regulations.

(i) *Place of employment* means any coal or other mine, factory, plant, establishment, construction site, or other area, workplace or environment where work is performed by any employee of an employer.

(j) *MSHA District Office* means any one of the Mine Safety and Health Administration's District Offices.

(k) *BOM* means the Bureau of Mines, Department of the Interior.

(l) *Employee* has the same meaning as stated in the OSH Act and for the purposes of this part includes *miner* as defined in the FMSH Act.

(m) *Employer* has the same meaning as stated in the OSH Act and for the purposes of this part includes *operator* as defined in the FMSH ACT.

[41 FR 45002, Oct. 14, 1976, as amended at 45 FR 2654, Jan. 14, 1980]